Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM)

Terrestrial Workgroup Report: VI. Preliminary Conclusions and General Recommendations

Summary of the ECOFRAM Process

In response to the Scientific Advisory Panel's recommendations, the Ecological Committee on FIFRA Risk Assessment Methods was initiated to expand the pesticide risk assessment process to include probabilistic risk assessment tools and methods. In doing so, the ECOFRAM began by evaluating the primary goal of a pesticide ecological risk assessment and identifying the resources the assessment is designed to address. Assessment endpoints were identified which were obtainable and would provide a broad estimation of the ecological consequences of pesticide applications. Current EPA risk assessment methodology was discussed as to its strengths and limitations and a basis was formed for further discussion on approaches to explore for increasing the usefulness and validity of risk assessment outputs.

Early in the process, ECOFRAM realized the enormity of the task and consciously elected to focus on avian acute effects. Further refinement was conducted in that only the dietary route of exposure was addressed to any depth. The exposure subgroup focused on refining a dietary exposure equation developed by Pastorock (199?) by evaluating individual components of avian behavior and the physical environment which effect potential exposure. As presented in previous posters in this session, individual components were further subdivided to evaluate the potential for introducing distributions for variables that would allow for constructing probabilistic models. Through sensitivity analysis, the refined equation can be used to identify variables that will provide the basis for identifying variables that most affect the risk assessment thereby directing further research. However, this exercise also identified the poor quality of the data for use in probabilistic risk assessments and exposed areas where large improvements could be made in the quality of the data.

The Effects Subgroup began by identifying and evaluating the sources of uncertainty which effect the assessment output. Currently required toxicity and environmental fate data were evaluated for their applicability in probabilistic models and recommendations were identified which would reduce the uncertainty associated with extrapolations from the laboratory to the field. Dose-response models incorporating uncertainty factors were constructed for single and multiple species for predicting mortality to a given species or a range of species. Finally, the exposure subgroup produced a tiered approach for risk characterization through the integration of acute toxicity data distributions with estimates of exposure distributions.

ECOFRAM made a conscious decision to concentrate efforts on dietary exposure and to focus on birds. ECOFRAM made this decision because it was recognized that while dietary exposure may be the primary route of exposure for most species and exposure scenarios, other routes including dermal and inhalation could be equally important in some situations. ECOFRAM strongly recommends that further work be directed at additional exposure routes, perhaps using or modifying methods suggested by this workgroup.

The science of probabilistic risk assessments is still in its infancy with years of development before it. However, the methodology developed by the ECOFRAM will begin the process of providing probabilistic risk assessments to the risk manager, providing them an indication of the magnitude of predicted ecological effects of pesticide application.

Levels of Refinement

The basic approach taken by the ECOFRAM is one of "Levels of Refinement." At every stage of the assessment process a hierarchical framework has emerged. The table illustrates the general refinement process throughout the risk assessment process identified by the ECOFRAM. The importance of population effects were recognized but not addressed in the process. It is important to note that these tiers may not be progressed through at the same rate. For instance, the data available for assessing exposure may be the quantity and quality for a level 3 assessment but the effects data may be lacking and only appropriate for level 1.

Recommendations

The Terrestrial ECOFRAM Work Group is still developing and discussing final recommendations and conclusions. The following points have been developed based on the draft report and discussion to date and are not inclusive. They are presented to provide some insight into the direction the work group is taking and to provide additional topics for the Interactive Session that follows this Poster Session.

ECOFRAM identified many areas that are critical to further development of probabilistic risk assessment methods. Recommendations for continuing this process were identified in the areas of problem formulation, study design, modeling and validation.

Scope of Current Probabilistic Applications

*The workgroup felt that progress could be made in improving the quality of pesticide risk assessments with today's models and data. However, given the limitations of data and the understanding of natural systems, the greatest confidence is in predicting acute lethal effects, and even here a great deal of work is needed.

*Chronic assessments could be conducted with the methodology identified or developed by ECOFRAM, but because of the limitations of the reproductive data available to the agency, these assessments should be evaluated with caution and should be limited to exceedence type assessments.

*Population level assessments are beyond the scope of data provided or available to the EPA at this time. The absence of data on the numerous variables that are needed to model population effects and the cost and difficulty of conducting a population level study, makes it a large challenge to develop models that address population level effects. ECOFRAM recommends that a research program be initiated that addresses this challenge.

Test Suitability

Acute Oral Test

*Acute oral test procedures should consider setting more test concentrations near the lethal threshold to reduce the variability around the LD50 estimate.

*To reduce the uncertainty associated with interspecies extrapolation, additional definitive acute oral test are needed on additional species. The Approximate Lethal Dose (ALD or UP and Down) method may have applicability to reducing uncertainty associated with interspecies extrapolation. However, the correlation between ALD and a definitive LD50 test must be thoroughly evaluated prior to adopting this approach.

*ECOFRAM recommends that research be initiated to better define the relationship of acute oral laboratory tests and field effects.

Acute Dietary Test

*Design the LC50 test to determine the daily dosage in mg/kg/day by allowing for a measurement of individual food consumption. This would provide an initial indication of food avoidance.

*Experimental design should be flexible to account for temporal pattern of effects and the determination of an incipient LC50.

*ECOFRAM recommends that research be initiated to better define the relationship of acute oral laboratory tests and field effects.

Avian Reproduction Test

*ECOFRAM concluded that the uncertainties inherent in extrapolating from laboratory reproduction test to the field are too great to justify redesigning the methodology at this time.

*ECOFRAM recommends that research be initiated to improve our understanding of the relationship of laboratory reproduction effects and field effects. Further, as we understand this relationship better, developmental work is needed to modify the current test design to support probabilistic risk assessments.

*Reproduction tests for additional species need to be developed if assessments are to address other groups of species with reasonable certainty.

Proof of Concept

The workgroup acknowledges that none of the concepts or recommendations made as a result of the effort has been verified or validated. It is strongly recommended:

*That the Agency and private organizations continue to develop these ideas.

*Initiate case studies to evaluate the concepts and methods presented and discussed in the ECOFRAM report.

*Individual sub-components of these models should be evaluated separately for their merit and accuracy of predictive capability.

*Fieldwork should be started or continued which will provide refined estimates of the dietary exposure equation.

*Model validation and development should continue for effects characterization.

Levels of Refinement				
	Level 1	Level 2	Level 3	Level 4
General Framework	* Deterministic Inputs * Deterministic Outputs * Simple models * Conservative Assumptions * Ignore minor pathways and effects * Use only standard studies * Use only Existing Field Data			* Probabilistic inputs * Probabilistic outputs * Complex models * Assumptions Replaced by data * Include all significant pathways and effects * Include special studies when needed * Include focused field studies when needed
Assessment Endpoints	Individual Survival & Reproduction			
Measurement Endpoints	LD50 and LC50 (with slope and confidence intervals), NOEL (clutch size, hatching success etc.) Quantity and quality of the data increase with successive tiers			
Exposure Characterization	Worst case based on means, generic species, existing data, gorging and non-gorging scenarios	Hypothetical distributions for literature (or means if available), focal species	Actual distributions from literature, focal species relevant to crop, relevant exposure scenario	field studies, relevant species, temporal and spatial analysis
Effects Characterization Method	Modified Pastorock Equation			
Exposure Characterization Output	Point estimates for acute toxicity in gorging and non-gorging scenarios	Distribution of acute toxicity estimates in gorging and non-gorging scenarios	Improved distributions of acute toxicity estimates in gorging and non-gorging scenarios based upon more data	Field data on focal species and consideration of landscape factors in spatially explicit models
Effects Characterization Methods	**METHOD 1** Point Estimates Quotients	**METHOD 2** Comparison of distribution of exposure to a point estimate of effects with uncertainty factors	**METHOD 3** Comparison of distributions of exposure and effects with uncertainty factors	**METHOD 5** Integration of exposure and effects distributions using Monte Carlo Analysis
Exposure Output	Point estimates for acute toxicity in gorging and non-gorging scenarios	Distribution of acute toxicity estimates in gorging and non-gorging scenarios	Improved distributions of acute toxicity estimates in gorging and non-gorging scenarios based upon more data	Field data on focal species and consideration of landscape factors in spatially explicit models
Effects Characterization Output	* Acute: 1 LD50 dose-response* * Dietary: 2 LC50 UF* * Repro: 2 NOELs	* Acute: 2-3 LD50 UF* * Dietary: 2 LC50 UF*, individual caging * Repro: 2 NOELs	* Acute: 4+ LD50* UF * Dietary: 2 LC50* UF*, individual caging, vary exposure * Repro: 2 NOELs, vary exposure, aviary study	Field conditions but only in combination with exposure assessments
Risk Characterization				
Spatial	Treated Field (Pt = 1), generic species, generic crop, gorging/non-gorging, dietary and Repro., label maximum rate	Treated Field and Non-target Areas (Pt < 1), focal species, generic crop or linked to focal species, gorging/non-gorging, dietary and repro., label maximum rate	Treated Field & Non-target Areas & Drift Zone (Pt < 1), focal species, generic crop or linked to focal species, gorging/non-gorging, dietary and Repro., label maximum and typical rates	Landscape (clumping, explicit, sizes, pesticide market), focal species, crop linked to focal species, gorging/non-gorging, dietary and repro., label maximum and typical rates
Risk Characterization Method	Deterministic Quotients	* Acute: Methods 2, 3 and 5as appropriate * Dietary: Methods 2, 3 and 5 as appropriate * Repro: Methods 2		
Risk Characterization Output	Quotient	Probability distribution specific to method selected		